



**National Institute for
Health Research**

FAMILY MEMBER/CARER INFORMATION SHEET, PHASE 1 #2

Understanding shared decision making about major surgery: second interview

Version 1.2, 13 December 2018

You, or a person close to you, previously participated in the early stages of our research study. We would now like to invite you to participate in a final, follow up interview. Before you decide, it is important that you understand why this part of the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

We are the same research team that you spoke to your family member/close friend before. We are from the University of Oxford, working with doctors and nurses at [INSERT SITE NAME] to study the process of shared decision making for patients contemplating major surgery who may be considered 'higher risk' due to age and / or other medical conditions e.g. heart, kidney, lung problems. This study is the first part of a larger research programme, funded by the National Institute of Health Research, to develop ways of optimising shared decision making for major surgery.

Our research team aims to understand: (a) the reasons people choose or decline major surgery and to see how these change over time; (b) what shared decision making really means for patients, families and clinical teams; (c) the information patients and doctors exchange before and after surgery, and (d) how this shapes shared decision making.

By doing this research we are seeking to develop potentially new and better ways of ensuring patients and doctors engage in shared decision making when considering major surgery.

Why have I been invited?

Someone close to you has agreed to participate in the study and has asked you to support them in their participation. We previously interviewed this person (you might have been included in that interview) and recorded a consultation between this person and their surgeon about the decision to undergo surgery or not. We are getting in touch three to six months after this surgery, or decision not to have surgery, because we would like to talk to you, and/or the person making that decision, one final time.

Do I have to take part?

No, taking part is entirely voluntary and you can withdraw at any time if you later change your mind, without giving a reason. Withdrawal will not affect the current or future clinical care of the person close to you in any way, as the research team is separate from their medical team.

What will happen to me if I decide to take part?

Our researcher will interview you, as requested by your family member/close friend, about how they have been since surgery, what you both think about the decision to have surgery and how satisfied or not you both are with the decision making process a few months later. With your permission, the researcher would like to tape (audio) record the interview. The interview can be held at your home or at another place of your choosing (e.g. the hospital), whichever you and the person close to you prefer. It will last no more than 1 hour.

What should I consider?

The main thing to consider is whether you are comfortable with researchers asking you questions about the decision about surgery; also, whether you are comfortable with that being audio-recorded.

Are there any possible disadvantages or risks from taking part?

The main disadvantage of the interview is we are asking you to commit some time and we will ask questions about your views about the decision your family member/close friend has made.

What are the possible benefits of taking part?

The main benefit of taking part in the research is that you will have an opportunity to contribute to a programme of research that should improve shared decision making about major surgery for other people.

Will my taking part in the study be kept confidential?

Yes. All data from the study will be made anonymous. They will be kept on a secure part of the server at the University of Oxford and only accessible by the research team. In those stored data, you will be referred to only by a code name ('pseudonym'). We will keep a separate paper record in a locked cabinet of participants' real names and corresponding code names. Audio recordings may be processed by a transcriber with a contractual agreement with the University. Transcribers are subject to the same requirements of confidentiality as researchers. They will have no other identifying information about you, and will not retain the audio recordings. Responsible members of the University of Oxford and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

In the unlikely event that there were concerns raised about your family member/friends care or safety during the course of the interview we would need to notify the appropriate members of the NHS organisation providing their care. We would discuss this with you before doing so.

Will I be reimbursed for taking part?

No, and since the interview will likely take place in your home, we do not anticipate you incurring any travel or expenses.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from interviews and observations and will use the minimum personally-identifiable information possible. We will store de-identified research data, audio recordings, and any research documents with personal information (such as consent forms) securely at the University of Oxford for up to six years after the end of the study. This will ensure that we have time to analyse it all, write papers and reports.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>

You can find out more about how we use your information by contacting Sara Shaw, Chief Investigator for the study, using the contact details at the bottom of this Information Sheet.

What will happen if I don't want to carry on with the study?

You can stop at any time. Participation is voluntary and even if you originally said yes, you may change your mind at a later stage. If you withdraw from the study, unless you state otherwise, any interview material that has been collected will be used for research as detailed in this participant information sheet. You are free to request that your data are destroyed at any time during or after the study.

Withdrawal from the study will NOT affect the care you or your family member/close friend receive from the NHS now or in the future.

What will happen at the end of the study?

We will analyse the data and write some papers and reports, including a 'lay summary'. We will provide you with a summary of the findings if you would like us to. You will not be identified from any report or publication placed in the public domain.

Some of the research being undertaken may also contribute to the fulfilment of an educational requirement such as a doctoral thesis.

What if you find something unexpected?

If anything you tell us in an interview has a direct bearing on the clinical care of your family member/close friend (for example if you disclose to us that they have a new symptom), we may inform their clinical team, as appropriate. In the unlikely event that you were to inform

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us of any concerns or complaints you had about your family member/friends care we would advise you on the appropriate complaints processes to follow, or we would notify the appropriate managers in the organisation providing your care.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Sara Shaw whose details are given below, or Professor Trisha Greenhalgh (Professor Shaw's line manager, same address). Alternatively, you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrig@admin.ox.ac.uk.

How have patients and the public been involved in this study?

People with experience of having to make decisions about surgery were involved in helping design this study and have also checked this information sheet and consent form.

Who is organising and funding the study?

The study is funded by National Institute of Health Research (NIHR). It is part of the *Optimising Shared decision-making for high Risk major Surgery* (OSIRIS) research programme. The study team is led by Professor Sara Shaw, who works at the University of Oxford; she is also custodian of the study information.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by [INSERT NAME OF RESEARCH ETHICS COMMITTEE]. The reference number is [INSERT].

Further information and contact details:

Please contact the following individual if you would like further information.

Professor Sara Shaw (Chief Investigator)
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University of Oxford
Radcliffe Observatory Quarter
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Oxford OX2 6GG

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Thank you for considering taking part.